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To study the problems faced by innover from conception idea to filling patent in Indian pharmaceutical industry

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Abstract

India's pharmaceutical sector is currently undergoing unprecedented change. India ratified the agreement establishing the World Trade Organization (WTO). This Agreement, inter-alia, contains an Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) which lays down minimum standards for protection and enforcement of IPR which are required to promote effective and adequate protection of IPR with a view to reducing distortions. Much of this is due to the country's introduction, on January 1, 2005, of a system of product patents; before that, only patents for processes were permitted to be issued. The purpose of this research paper is to study the problems faced by innover in filling patent in Indian pharmaceutical industry. The paper also includes study of problem related to research and development activities, patent filling process etc.

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Keywords: Amendment; innovation; IPR; Pharma companies

1. Introduction

The introduction of the product patent law in India from January 01, 2005 has been a fundamental change in the Indian pharma industry. The law is expected to put an end to some of the earlier practices followed by Indian

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companies and prompt them to focus on discovery led research to introduce patented molecules**.** India's entrepreneurial pharmaceutical manufacturers are now beginning to leverage benefits from the introduction of the nation's product patent system on January 1, 2005. Most will be unable to develop the financial muscle necessary to embark on R&D for innovative new products, but their scientific, technical and manufacturing skills, developed under the country's 25-year process patent system, perfectly match the requirements of global drug manufacturers that are increasingly seeking to offshore many research and manufacturing activities previously performed in-house. The lack of patent protection made the Indian market undesirable to the multinational companies that had dominated the market, and while they streamed out. Indian companies carved a niche in both the Indian and world markets with their expertise in reverse-engineering new processes for manufacturing drugs at low costs. Although some of the larger companies have taken baby steps towards drug innovation, the industry as a whole has been following this business model. Patent amendment should be favored for the patent protection India which will in turn India an ideal center for the research and the domestic manufacturers will be benefited but the loopholes in it should be rectified for the all round development.

2. Research Problem and Questions

This problem (questions) can be split into the following questions:

a) How companies are captivating amended intellectual property act 2005?
b) What is various research & development and business strategies have been adopted by Indian pharma industry to sustain business after the issuance of patent ordinance in 2005?
c) Are pharmaceutical companies finding any complicatedness in overall patent filling process?

3. Importance of the Study

In order to be evidence for the Indian Pharma companies in a path that have huge benefits by amended Patent act on the marketing activity in the way that best fit the consumers. This study will be useful for providing factors that mostly affect the Indian pharma companies for patenting the molecule.

4. Objectives of the Study

- To study the impact of intellectual property rights through innovation in pharma drug manufacturing companies.
- To focus on the various strategies adopted by Indian pharma industry to sustain business after the issuance of patent ordinance in 2005.
- To study problems Indian pharma companies are facing in overall patent filling process.

5. Research Limitations

a) The study was restricted to pharmaceutical industry located around Mumbai and Pune region, lawyers and

doctors located in Pune.

b) The study focused on pharmaceutical industry and Amended patent act 2005 only and hence results of the analysis are not applicable to any other type of industry.

6. Literature Review

The research article by CBO Study discusses about research and development cost, time and risk. Research and development requires huge capital investment at the same time, the risk is high in research and development activity in the form of success which means the cost of successes and failures alike. Even time require is long as 11.8 years to come up with patented product. According to the pharmaceutical company have various strategy like instead of going for mew molecule they modify existing molecule. The strategy depends on company policy of profitability. The research article by Hemant N. Joshi discusses on the problem which Indian pharmaceutical companies are facing. Research and development activity demands huge capital investment, skilled people, technology etc (around $300 million to $ 600 million of investment) where success rate is even very little. Indian pharmaceutical companies have skilled people, strong IT back up, technology but is deficient in capital investment. Even Due to Amended patent act 2005, which globally harmonized patent system that prohibit the replication or reverse engineering of patent protected new drugs, patent holding companies are enjoying monopoly. This is affecting availability & affordability of patented drugs to common Indian customers.

The research article by Ravi Kiran, SunitaMistra discuss about the R & D activity and patenting activity of Indian pharmaceutical companies post TRIPS period. The study by Gupta (2000) highlights that after the establishment of WTO; there is a greater effort by the Indian R&D organizations to obtain patents in USA. Kubo (2004) opines that R&D intensity and patent to R&D ratio has increased in India after 1995 for large pharmaceutical firms. Grace (2004) is of the opinion that most successful firms investing an increasing amount in R&D including in partnership with MNCs, & with increasingly positive results. Dhar & Gopakumar (2006) also accept that there has been an increase in the R&D spending of some of the leading firms, in particular, Ranbaxy and Dr Reddy's. As a result, R&D intensities of the firms have improved. The article by Richard E. Rowberg talks about the cost allocation of the R & D department. As discussed above the research and development department demands huge capital investment. Cost allocation plays very important role in research and development activity which depends on company strategy. India's leading drug manufacturers are becoming global players, utilizing both organic growth, through the gradual development of their business, and mergers and acquisitions(M&A) as they seek to boost their presence in existing markets and open up new ones. However, there are significant obstacles ahead, & overcoming them will require new commitment by both industry & government, & unprecedented levels of partnership between them.

7. Research methodology

Research design: Descriptive research design.

Population: Indian pharmaceutical companies, lawyers and doctors

Sampling Area: Mumbai and Pune region

The term Mumbai and Pune Region used in this study refers to area carved out by the pharmaceutical industry for its high rate of development. Mumbai and Pune region as understood in the Pharmaceutical Marketing phraseology is quite a large area spread over. There are around 300 pharmaceutical companies which are catering to the population of this area. Hence it was possible only to obtain data from the representatively selected top 25 pharmaceutical companies based on purposive sampling, in Mumbai and Pune region, having major market share. Doctors with different specialization like radiologist, gynecologist, cardiologist etc and practicing since 8 years are considered from Pune city. Patent experts practicing in private firms are contacted to collect information, whose experience is more than 10 years in Pune city.

Sampling Technique: Non-probability purposive sampling for pharmaceutical companies, stratified convenience sampling for lawyers and doctors

Sample Size: Total -60

Doctors – 30 with different specializations

Patent Experts – 5 practicing in private firms

R and D, Legal department etc of Indian pharmaceutical company – 25

Research Instrument: Personal Interview, structured Questionnaire

Tool: With a view to obtain data from the field, three different questionnaires designed , one for the pharma companies managers, second for patent experts & the other for doctors, have been prepared & administered. The responses received have been tabulated & statistically analyzed.

E sources: Internet, sites, journals, publications, articles, online research papers etc.

Data Analysis procedure The field survey and personal interview technique adopted for data collection and collected data has been tabulated and presented with the help of graphs, tables and charts. Both descriptive and inferential statistics were used in presenting and analyzing the data. Descriptive tools such as frequency counts, mean scores, percentages were calculated for the statements on the questionnaire in order to determine the impact and its related issues.

8. Data analysis

a) What are the different strategies you are using for research and development department?

i. Own department is working actively

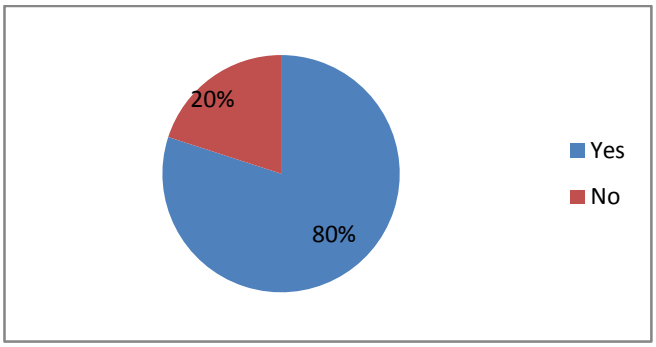
ii. Collaboration withpharma company, government, NGO, WHO , Educational institutes

iii. Outsourcing
iv. Risk sharing partnership
v. Agreement with foreign companies.
vi. Hived off of R and D activity into different entities.
vii. merger of R and D units
viii. Attract investment
ix. Any other suggestion

Outcome: 5% own department working actively, 18 % collaboration with the other companies, 9 % outsourcing, 8% agreement with foreign companies, 12 % risk sharing partnership, 10 % hived off research and development activity, 10 % merger of R & D units, 8 % attracting investment.

Interpretation- The different strategies of Indian pharmaceutical company are using for research and development department.

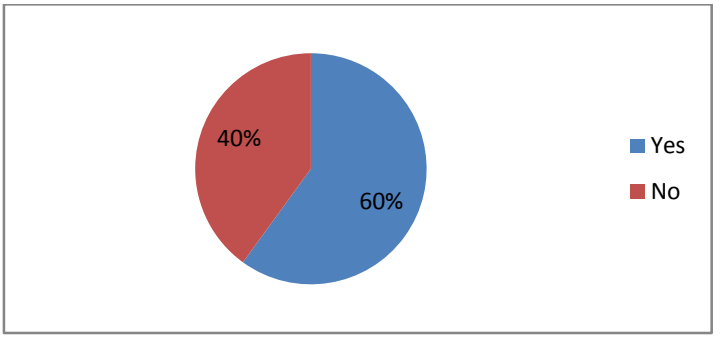
b) Indian intellectual property right system is user friendly.



Outcome- 80 % of the total says that IPR system is user friendly. Still there are some loopholes in it.

c) Process of filling patent is user friendly.

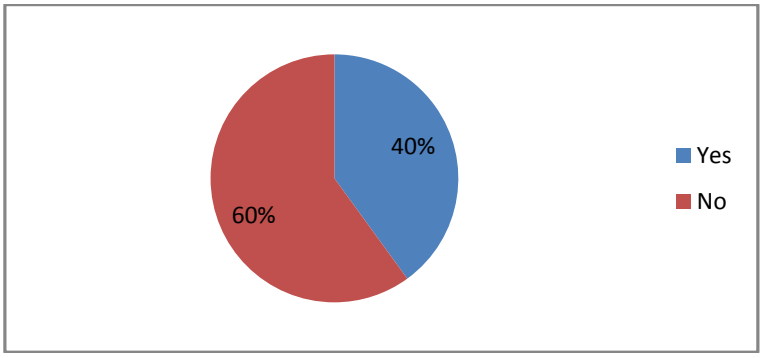
Yes No



Outcome- 60 % of the total says that process is fine.

d) Period required to register to patent is more than required.

Yes No



Outcome- 40 % of the total says that period required to register is more than required.

Interpretation- IPR system is useful due to its user friendliness. The reduction in Period required to register patent will be of great use.The lengthy time period between patent filing and placing a product on the market means that pharmaceutical manufacturers receive far shorter periods of patent exclusivity than is the case for other patent dependent industries.

5. Problems faced by pharmaceutical companies while registering IPR.

a. Documentation
b. Financial support for innovation
c. Technology
d. Unavailability of R and D center

Outcome- 36 % documentation, 27% financial support,27% technology, 10% unavailability of R and D are problems while registering IPR.

Interpretation-Documentation, Financial Support & Technology these are the major problem areas faced by pharmaceutical companies while registering IPR.

6. Rank the following problem in ascending order in inventing patented molecule drug

a) Research and Development facility
b) More time require for innovation
c) Huge capital investment
d) Lack of Human resource
e) Insufficient venture capital funding
f) Paucity of trained person
g) different private equity market
h) Early stage funding.
i) Any other

Outcome- 22% R & D facility,19% more time require for innovation,18% huge capital investments, 6% lack of human resources, 8% insufficient venture capital funding, 5% paucity of trained person, 9% different equity market, 13% early stage funding.

Interpretation -Research and Development facility, more time require for innovation, huge capital investments are the top 3 Problems in inventing patented molecule.

9. Finding and conclusion

a) According to the research study for R and D and business strategies, pharmaceutical industry is adopting various strategies depending on company's policy. The implication which comes out is that the present situation is challenging, but at the same time it throws up several new opportunities for Indian pharma companies. What worked in the past may not necessarily hold them in good path in the future. Companies which take advantage of the fundamental changes, that industry go through and re-jig their strategies accordingly will be able to successfully steer the future in Indian pharmaceutical company.
b) The finding which comes out from the study is that Indian intellectual property right system is user friendly to Indian pharmaceutical company.
c) The finding which comes out from the research is that process of filling patent to some extend is user friendly to Indian pharmaceutical company.
d) The lengthy time period between patent filing and placing a product on the market means that

pharmaceutical manufacturers receive far shorter periods of patent exclusivity than is the case for other patent dependent industries. The inference which comes out from the analysis is that period required to register patent is averagely more than required time.

e) The filing of a patent application is the first step in securing a patent. If the application is submitted with the Patent Office, the officer then starts publication and examining the authenticity of invention. If everything is in order, the patent would be granted to the inventor. According to the research study about problems faced by pharmaceutical companies while registering IPR commonly is Documentation work, financial support, Technology, Unavailability of R & D center. The implication which comes out from the analysis is that documentation, financial Support & technology these are the major problem areas respectively faced by pharmaceutical companies while registering IPR.

f) The inference that comes out is R & D facility, more time requires for innovation and huge capital investment are the top 3 major problems to Indian Pharma Company in inventing patented molecule.

10. Suggestions

a) Indian Pharmaceutical sector looks extremely positive. They can adopt various strategies to increase R & D activity as, Contract Research and Manufacturing Services (CRAMS), Contract Clinical Trials, Global alliances & M&A's, Industry academic collaboration, improving the Quality of Public Research etc looking at the resources.

b) Giving India the IPR edge: Problems faced by Indian pharmaceutical companies while registering IPR commonly are documentation work, financial support, Technology, unavailability of R & D center while registering IPR. Following are the suggestions as,

c) There is a need to expedite for the process of examining the patent application to stimulate innovation. b. A time limit for filing & disposing of pre-grant oppositions should be provided at the earliest.

d) Pharmaceutical must improve its R&D productivity and its legal framework must be altered to promote innovation and discourage imitation and prove that its products really work and provide value for money.

e) Provide financial incentives to encourage innovations & research.

f) Different institutions should be funded for undergoing research. The Indian education system and the industry need to come together to plug the shortage, which will require significant investment.

Possible options for IPI

As far as India's pharmaceutical industry is concerned, various options are possible in the WTO regime.

These are to:

(a) Manufacture off patented generic drugs,

(b) Produce patented drugs under compulsory licensing or cross licensing,

(c) Invest in R&D to engage in new product development,

(d) Produce patented and other drugs on contract basis,

(e) Explore the possibilities of new drug delivery mechanisms and alternative use of existing drugs, and
(f) Collaborate with multinationals to engage in R&D, clinical trials, product development or marketing the patented product on a contract basis and so on.

Besides these strategies, India's strength lays in process development skills. This expertise utilized within the WTO framework with emphasis on quality standards will provide India a competitive advantage over other Asian countries.

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